



11th March 2025

URGENT: FIELD SAFETY NOTICE – MDS-24-5154-B

4Fr Single Lumen PowerPICC (SOLO and non-SOLO versions)

REF: See Appendix 1 **Lot Numbers:** See Appendix 1

Type of Action: Product Removal

Attention: Clinical personnel involved in the placement of central vascular devices including but not limited to: Anesthetist, Intensivists, Interventional Radiology, Vascular Access Specialists & Teams, Risk Managers, Purchasing Managers

This letter contains important information which requires your immediate attention.

Dear Customer,

In October 2024, BD issued an advisory Field Safety Notice for unexpired lot numbers of 4Fr Single-Lumen PowerPICC Catheters (SOLO and non-SOLO versions) to inform customers about an observed increase of material fatigue leaks (Figure 1) on the 4Fr Single Lumen PowerPICC catheters in specific geographies.

BD is now conducting a Field Safety Corrective Action to remove specific lots of **4Fr Single-Lumen PowerPICC Catheters** listed in Appendix 1.

NOTE: If you are not impacted by the specific lots being removed as per Appendix 1, this Field Safety Notice contains important information and actions for all customers of 4Fr Single-Lumen PowerPICC catheters.

Description of the problem

BD has conducted a comprehensive investigation and has identified that three lots of resin used to extrude the tubing material exceeded our supplier's specification for a material property called Melt Flow Index (MFI). BD's investigation has shown that higher MFI could lead to increased material fatigue leaks. All of the extruded catheters meet BD specifications for dimensions and mechanical properties; however, BD is removing all product from the field that was extruded from resin that exceeded the supplier specification.

Although the increase in complaints is limited to specific geographies, the product with higher MFI has been distributed worldwide, therefore all impacted lots are being removed from the global market.

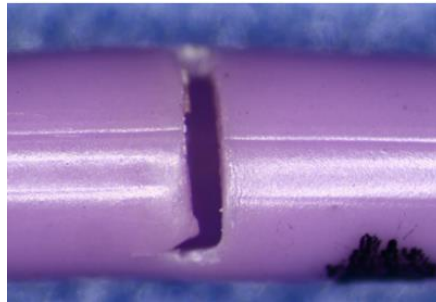


Figure 1: Example of transverse/circumferential crack in the catheter body

BD has identified two additional contributing factors to the increase in material fatigue leaks seen on the 4Fr Single Lumen PowerPICCs in some geographies. Each factor must be controlled in order to minimize the failures.

Securement Systems:

After engineering analysis and analysis of returned leaking devices, BD has concluded that use of compression style securements has the potential to damage the catheter and cause leaks. A higher number of complaints have been reported from facilities and regions utilizing compression style securement systems. BD is highlighting the following in order to reduce the failures:

- BD strongly recommends the use of adhesive backed securement systems (e.g. Statlock) instead of 'compression style' securement systems.
- Securement systems should be appropriately sized to accommodate the increase in diameter of the catheter in the taper region.

Catheter Insertion and Dressing:

BD PICCs have a reverse taper which increases in diameter near the 0 marking on the device.

- Fully inserting the PICC device into the patient, as close as possible to the zero mark (position B in Figure 2), including the kink-resistant, reverse tapered region at the insertion site, is associated with lower leakage rates. To determine corresponding compression style size see figure 2, which shows that for the 4 Fr PICC, the size will be between 4 to 6 Fr, depending on the position of the securement device relative to the taper.

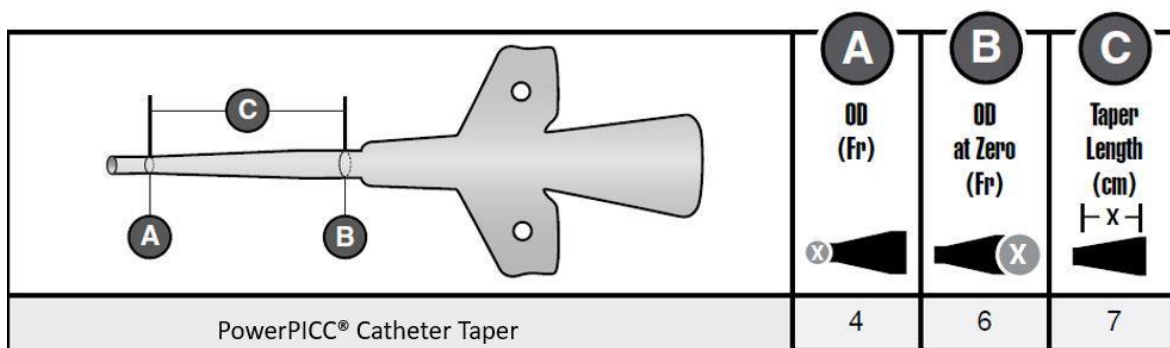


Figure 2: Image of the PowerPICC Taper Region



- Please note, using the J-loop technique when placing or dressing the catheter prevents insertion to the 0 mark and the use of this kink-resistant, reverse tapered region at the insertion site. See Figure 3 for an image of the J-loop. Where possible, refrain from using this technique.



Figure 3: Image of the J-loop

Clinical risk

The current issue is that there has been an increased number of complaints related to PICC fracture and breakage with regards to the 4Fr single lumen PowerPICC and PowerPICC solo. The risks associated with this issue are as follows: infiltration, extravasation, discomfort, phlebitis, bleeding, air embolism, foreign body embolism, infection and interruption to therapy.

The risks outlined above may require future medical procedures such as retrieval of a foreign body embolism, replacement of the PICC line and other treatments as necessary as deemed appropriate by the health care provider.

Patients and users should take notice to their PICC lines for any signs or symptoms that may be consistent with catheter fracture or breakage. These signs and symptoms may manifest but are not limited to: pain upon infusion, swelling of the arm not related to DVT, inability to withdraw blood, and leakage of infusate around the insertion site. Use clinical judgement to determine if explanting the device is necessary and any devices remaining in situ should continue to be monitored with current good clinical practice, looking out for the signs and symptoms mentioned above. If a fracture or breakage is noticed, the PICC should be removed as soon as medically possible for the patient.

From June 2023 when BD started to see an increase in complaints through December 2024, the global complaint rate for material fatigue leak is 0.058%. All complaints have been assessed for regulatory reportability and reports have been made, as applicable.

Clinical User Actions

BD is not recommending to explant product in-situ from any lots (including those being recalled). Consider the patient's infusion needs, alternative access options and the risks and benefits of continued catheter usage. The following additional advice is recommended

Actions if catheter damage is not suspected:



1. Carefully examine the visible portion of the catheter to assess for any sign of damage to the catheter shaft.
2. Monitor the patient closely for signs and symptoms of catheter damage, such as increased extremity circumference, infusate leakage, or reports of pain.
3. If using a compression style securement device, consider replacing it with an adhesive-backed securement system to reduce the risk of material fatigue. Ensure securement systems are appropriately sized to accommodate the increase in diameter of the catheter in the taper region.
4. Ensure the catheter is positioned correctly, with the kink-resistant, reverse tapered region at the insertion site, to minimize the risk of leaks. Note that if the catheter is currently positioned with the kink-resistant, reverse tapered region external to the patient, it is not advisable to reposition it internally. Instead, be aware that not using this region may increase the risk of leaks. Use clinical judgment to decide whether to continue using the device or to replace it.

Actions if catheter damage is suspected:

1. Immediately stop any infusion if catheter damage is suspected.
2. Follow your institution's guidelines for catheters with suspected damage.
3. If the catheter is confirmed to have a fracture or break, the catheter should be removed and an alternative route for access should be obtained.

BD Actions

- BD is removing all unexpired lots of 4Fr Single Lumen PowerPICC which exceed the supplier's specification for MFI.
- BD is notifying users that adhesive back securement systems are recommended.
- BD is notifying users that if they do use compression style securement systems, they must be sized appropriately to accommodate the reverse taper.
- BD is notifying customers to insert the catheter to as close as possible to the 0 mark, per the IFU.
- BD has been updating the product IFU with cautions related to the use of compression style securement systems around the taper region of the PICC.
- BD will provide product replacement or credit for all destroyed products.
- BD will continue investigating this issue and will follow up with any additional actions.

Customer Actions:

- Cease use of any unused affected lot numbers of **4Fr Single Lumen PowerPICC**.
- Identify and quarantine all unused affected lot numbers of **4Fr Single Lumen PowerPICC**.
- Make a note of the lot numbers and immediately destroy all unused affected units.
- Complete and return the Customer Response Form **even if you no longer have any inventory remaining in your facility by 11th April 2025**.
- Circulate this notice to all those who need to be aware within your organization or to any organization where the potentially affected products have been transferred.



- Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Distributor Actions:

- Cease distribution of any unused affected lot numbers of **4Fr Single Lumen PowerPICC**.
- Identify, quarantine, making a note of the lot numbers then destroy all undistributed affected lot numbers of **4Fr Single Lumen PowerPICC**.
- Identify the facilities where you have distributed affected product and notify them immediately of this notice.
 - Have your customers complete and return the Customer Response form to your organisation for reconciliation purposes by **11th April 2025**.
- Complete and return the Customer Response Form following completion of your reconciliation activities.
- Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

	End User with Inventory	End User with ZERO inventory	Where to send completed form
Purchased directly from BD	Complete the form in its entirety Upon receipt, BD will process the response, and you will receive replacements for unused product	Complete form and check the box indicating “no inventory”	BDFieldActions@bd.com
Purchased from a distributor/3rd party	Complete all fields on the form and contact your distributor to arrange for replacements	Complete form and check the box indicating “no inventory”	Return the form to your distributor

Contact reference person

If you have any questions about this, please contact your local BD representative or the local BD office.

We confirm that the appropriate regulatory agencies have been informed of these actions.

BD is committed to *advancing the world of health™*. Our primary objectives are patient safety and user safety and providing you with quality products. We apologise for the inconvenience this situation may cause you and thank you in advance for helping BD to resolve this matter as quickly and effectively as possible.

Sincerely,

Kinga Stolinska
Director, Post Market Quality
EMEA Quality



Customer Response Form - MDS-24-5154-B

4Fr Single Lumen PowerPICC (SOLO and non-SOLO versions)

REF: See Appendix 1 Lot Numbers: See Appendix 1

Return to BDFieldActions@bd.com as soon as possible or **no later than the 11th April 2025**.

I confirm this Field Safety Notice has been read, understood and that all recommended actions have been implemented as required.

Tick the appropriate box below

☐ We do not have any of the affected product as listed in **Appendix 1** in our facility. Affected product has been used.

All product that is not available for destruction will be considered as dispositioned at your location and therefore physically unavailable unless otherwise specified.

OR

☐ We have the following units of the affected product as listed in **Appendix 1** in our possession and I confirm that the units have been destroyed *(Please complete the table below with the lot number and the number of units destroyed. **Replacement** product will only be sent on completion and return of this form).*

REF:	Lot Number/s:	Units destroyed <i>(insert quantity below)</i>

Account/Organisation Name:	
Department <i>(if applicable):</i>	
Address:	
Postcode:	City:
Contact Name:	
Job Title:	
Contact Telephone Number:	Contact E-mail Address:
Name of your supplier for this product <i>(if not direct from BD)</i>	
Signature:	Date:

*This form must be returned to BD before this action can be considered closed for your account. *If you were forwarded this Field Safety Notice via a distributor/3rd party, please return your completed form to that organisation for reconciliation purposes.*



Appendix 1 – Impacted Product Codes / Lot numbers

Manufacturer's SRN: US-MF-000017720

Product Name	REF	Lot No.	Expiration Date DD-MMM-YYYY	UDI
4Fr Single Lumen PowerPICC	2174108	REGV1296	31-mar-25	(01)00801741138966(17)250331(10)REGV1296
		REGX0239	31-mar-25	(01)00801741138966(17)250331(10)REGX0239
		REGT6082	31-may-25	(01)00801741138966(17)250531(10)REGT6082
		REGU1733	30-jun-25	(01)00801741138966(17)250630(10)REGU1733
		REGU1669	30-jun-25	(01)00801741138966(17)250630(10)REGU1669
		REGV0410	31-jul-25	(01)00801741138966(17)250731(10)REGV0410
		REGX0214	31-aug-2025	(01)00801741138966(17)250831(10)REGX0214
		REGW3741	31-aug-2025	(01)00801741138966(17)250831(10)REGW3741
		REGX0215	30-sep-25	(01)00801741138966(17)250930(10)REGX0215
		REHN2402	30-sep-25	(01)00801741138966(17)250930(10)REHN2402
		REHS1080	30-sep-25	(01)00801741138966(17)250930(10)REHS1080
		REGY0240	31-oct-25	(01)00801741138966(17)251031(10)REGY0240
		REGZ0212	31-oct-25	(01)00801741138966(17)251031(10)REGZ0212
		REHN2423	31-oct-25	(01)00801741138966(17)251031(10)REHN2423
		REGZ1010	30-nov-25	(01)00801741138966(17)251130(10)REGZ1010
		REGZ2094	30-nov-25	(01)00801741138966(17)251130(10)REGZ2094
		REGZ1023	30-nov-25	(01)00801741138966(17)251130(10)REGZ1023
		REHN1419	31-dec-2025	(01)00801741138966(17)251231(10)REHN1419
		REHP1751	31-jan-2026	(01)00801741138966(17)260131(10)REHP1751
		REHR1459	31-mar-26	(01)00801741138966(17)260331(10)REHR1459
4Fr Single Lumen PowerPICC	2194108	REHT2240	31-may-25	(01)00889989030587(17)250531(10)REHT2240
		REHY2816	31-oct-25	(01)00889989030587(17)251031(10)REHY2816
4Fr Single Lumen PowerPICC	6174108	REGV3345	31-jul-25	(01)00801741139000(17)250731(10)REGV3345
		REGX1802	30-sep-25	(01)00801741139000(17)250930(10)REGX1802
		REGX2978	30-sep-25	(01)00801741139000(17)250930(10)REGX2978
		REGX0250	30-sep-25	(01)00801741139000(17)250930(10)REGX0250
		REGY0747	31-oct-25	(01)00801741139000(17)251031(10)REGY0747
		REGZ0061	31-oct-25	(01)00801741139000(17)251031(10)REGZ0061
		REHR1412	31-dec-2025	(01)00801741139000(17)251231(10)REHR1412
		REHR1507	31-Jan-2026	(01)00801741139000(17)260131(10)REHR1507
4Fr Single Lumen PowerPICC	6174118	REHR0101	31-mar-26	(01)00801741139000(17)260331(10)REHR0101
		REGS2786	31-mar-25	(01)00801741139017(17)250331(10)REGS2786
		REGS3903	30-apr-2025	(01)00801741139017(17)250430(10)REGS3903
		REGU1649	30-jun-25	(01)00801741139017(17)250630(10)REGU1649
		REGV1890	31-jul-25	(01)00801741139017(17)250731(10)REGV1890
		REGW0829	31-aug-2025	(01)00801741139017(17)250831(10)REGW0829
		REGX2261	30-sep-25	(01)00801741139017(17)250930(10)REGX2261
		REGX1063	30-sep-25	(01)00801741139017(17)250930(10)REGX1063
		REGZ1416	31-oct-25	(01)00801741139017(17)251031(10)REGZ1416
		REHR0058	31-dec-2025	(01)00801741139017(17)251231(10)REHR0058
		REHS1902	30-apr-2026	(01)00801741139017(17)260430(10)REHS1902



4Fr Single Lumen PowerPICC	6174335	REGW3468	31-aug-2025	(01)00801741139024(17)250831(10)REGW3468
		REGZ1452	30-nov-25	(01)00801741139024(17)251130(10)REGZ1452
		REHR1518	31-mar-26	(01)00801741139024(17)260331(10)REHR1518
		REHT3429	31-may-26	(01)00801741139024(17)260531(10)REHT3429
4Fr Single Lumen PowerPICC	6174355	REGX2134	31-oct-25	(01)00801741139031(17)251031(10)REGX2134
		REGW0830	31-oct-25	(01)00801741139031(17)251031(10)REGW0830
		REGV1927	31-oct-25	(01)00801741139031(17)251031(10)REGV1927
		REGV3426	31-oct-25	(01)00801741139031(17)251031(10)REGV3426
		REGW0745	31-oct-25	(01)00801741139031(17)251031(10)REGW0745
		REHR1446	31-jul-26	(01)00801741139031(17)260731(10)REHR1446
		REHS1932	31-jul-26	(01)00801741139031(17)260731(10)REHS1932
4Fr Single Lumen PowerPICC	6194355	REHU3309	30-jun-25	(01)00801741139079(17)250630(10)REHU3309
4Fr Single Lumen PowerPICC	22184118	REGX1035	31-oct-25	(01)00801741121579(17)251031(10)REGX1035
		REGZ1436	30-nov-25	(01)00801741121579(17)251130(10)REGZ1436
		REGX2200	31-dec-2025	(01)00801741121579(17)251231(10)REGX2200
		REHS1034	31-dec-2025	(01)00801741121579(17)251231(10)REHS1034
4Fr Single Lumen PowerPICC	CK000375	REHY0131	31-mar-25	(01)00801741102660(17)250331(10)REHY0131